

Remarks

Claims 1-17, 19 and 20 have been canceled. Applicants retain the right to pursue the canceled subject matter in one or more divisional or continuation applications.

Figure 1

The Examiner indicated that the two separate panels of Figure 1 should properly be labeled "Figure 1A" and "Figure 1B." Applicants respectfully submit that the amendments to Figure 1 overcome this objection.

Rejections under 35 U.S.C. §101/§112, first paragraph

The Examiner has rejected claims 21-91 under 35 U.S.C. §101 as lacking a specific and substantial credible utility. The Examiner has also rejected these claims under §112, first paragraph due to the lack of utility. Specifically, the Examiner alleges that the "application does not disclose a specific biological role for this protein or its significance to a particular disease, disorder [or] physiological process" (Paper No. 20040315, page 3). The Examiner further asserts that "[t]here is absolutely no evidence of record or any line of reasoning that would support a conclusion the a [sic] protein of the instant invention is associated in any way with the plurality of causally unrelated disorders that are listed on page 22 of the instant specification" (Paper No. 20040315, page 5). Applicants respectfully traverse.

Contrary to the Examiner's assertion, the application does disclose a specific biological role for the protein and a significance to a particular disease state. See, for example, page 24, paragraphs [0085] through [0087]. Thus, contrary to the Examiner's assertion, the instant case is not analogous to the situation in *Brenner v. Manson* (383 U.S. 519 (U.S. 1966)). In *Brenner*, the issue was not whether a disclosed utility was sufficient. Rather, the issue was that the applicant had failed to disclose any utility at all (*Id.* at 521). Furthermore, the disclosure of several uses for the claimed invention does not negate the specificity of any one of those uses. Indeed, the M.P.E.P. at § 2107.02 states "[i]t is common and sensible for an applicant to identify several specific utilities for an invention . . .". Further, "[i]f applicant makes one credible assertion of utility, utility for the claimed invention as a whole is established." *Id.* See also, *In re Malachowski*, 189 U.S.P.Q. 432 (C.C.P.A. 1976); *Hoffman v. Klaus*, 9 U.S.P.Q.2d 1657 (Bd. Pat. App. & Inter. 1988). Thus, the Examiner's assertion that the specification lacks specific utility because it provides a "plurality" of disorders is improper and immaterial.

Both Kyaw et al. and Im et al. describe the protein TDAG8, which is 100% identical to the claimed polypeptide. Figure 4 of Im et al. confirms the expression of the claimed G-protein coupled receptor in the lung and in leukocytes as mentioned on page 7, paragraph [0026]. Kyaw et al. support Applicants' assertion that the claimed polypeptide is a G-protein coupled receptor. Im et al indicate that the claimed G-protein coupled receptor is a receptor for psychosine and suggest that the claimed polypeptide plays a role in the white matter disease Globoid Cell Leukodystrophy (GLD; also known as Krabbe's disease), which causes dysmyelination, spasticity, seizures and cerebral degeneration. Im et al. also suggest (at page 432) that receptor blockers or antagonists may prove useful in treating such disorders.

1 Applicants note that supportive evidence dated after the applicants' filing date, "can be used to
2 substantiate any doubts as to asserted utility since it pertains to the accuracy of a statement
3 already in the specification." See e.g., *In re Brana* 51 F.3d 1560, 1567 at n19 (Fed. Cir. 1995)
4 Application No.: 10/084,206 16 Docket No.: PF191D1C1

Applicants respectfully submit that one of skill in the art would not consider the asserted utility to be "false," particularly in light of Kyaw et al. and Im et al. Applicants therefore request withdrawal of this rejection.

Rejections under 35 U.S.C. §112, first paragraph

The Examiner has rejected claims 29-37, 48-59, 68-75 and 84-91 under 35 U.S.C. §112, first paragraph as not complying with the Deposit requirements. Applicants hereby submit the following:

Human Genome Sciences, Inc., the assignee of the present application, has deposited biological material under the terms of the Budapest Treaty on the International Recognition of the Deposit of Micro-organisms for the Purposes of Patent Procedure with the following International Depository Authority: American Type Culture Collection (ATCC), 10801 University Boulevard, Manassas, Virginia 20110-2209 (present address). The deposit was made on June 1, 1995, accepted by the ATCC, and given ATCC Accession Number 97184. In accordance with M.P.E.P. § 2410.01 and 37 C.F.R. § 1.808, assurance is hereby given that all restrictions on the availability to the public of ATCC Accession Number 97184 will be irrevocably removed upon the grant of a patent based on the instant application, except as permitted under 37 C.F.R. § 1.808(b). A partially redacted copy of the ATCC Deposit Receipt for Accession Number 97184 is enclosed herewith as Exhibit A.

Rejections under 35 U.S.C. §102(b)

Claims 21-25, 27-34, 36-44, 46-56, 58-64, 66-72, 74-80, 82-88, 90-91 were rejected under 35 U.S.C. §102(b) as anticipated by Mattson et al (WO 98/32858). The Examiner alleges that the Mattson et al reference is properly cited as prior art because priority application Serial No. 08/468,534, filed June 6, 1995, (of which the instant application is a divisional) does not meet the requirements of 35 U.S.C. §112, first paragraph due to the outstanding rejection under 35 U.S.C. §101. Applicants respectfully traverse.

For the reasons provided above, Applicants respectfully submit that both the instant application and priority application Serial No. 08/468,534 comply with the requirements of both 35 U.S.C. §101 and 35 U.S.C. §112, first paragraph. Therefore, the instant application is entitled to priority to the filing date of the priority application (June 6, 1995) under 35 U.S.C.

§120. Because the cited reference has a publication date of July 30, 1998, which is after the priority date of the instant application, it is not properly cited as prior art. Applicants therefore request withdrawal of this rejection.

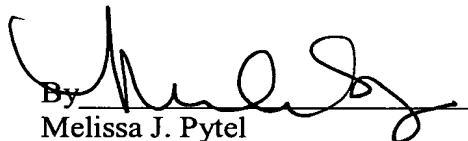
Conclusion

Entry of the above amendment is respectfully solicited. In view of the foregoing remarks, Applicants believe that this application is now in condition for allowance, and an early notice to that effect is urged. The Examiner is invited to call the undersigned at the phone number provided below if any further action by Applicant would expedite the examination of this application.

Finally, if there are any fees due in connection with the filing of this paper, please charge the fees to our Deposit Account No. 08-3425. If a fee is required for an extension of time under 37 C.F.R. § 1.136 not accounted for in the Petition for an Extension of Time submitted concurrently herewith, such an extension is requested and the appropriate fee should also be charged to our Deposit Account.

Dated: May 7, 2004

Respectfully submitted,

By 

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BUDAPEST TREATY ON THE INTERNATIONAL RECOGNITION OF THE DEPOSIT OF MICROORGANISMS FOR THE PURPOSES OF PATENT PROCEDURE

INTERNATIONAL FORM

RECEIPT IN THE CASE OF AN ORIGINAL DEPOSIT ISSUED PURSUANT TO RULE 7.3
AND VIABILITY STATEMENT ISSUED PURSUANT TO RULE 10.2

RECEIVED

JUN 23 1995

To: (Name and Address of Depositor or Attorney)

Human Genome Sciences, Inc.
Attention: Robert H. Benson
9410 Key West Avenue
Rockville, MD 20850

HGS LEGAL DEPT.

Deposited on Behalf of: Human Genome Sciences, Inc.

Identification Reference by Depositor:

ATCC Designation

DNA Plasmid, 563241 (HGS Docket PF191)

97184

The deposits were accompanied by: ☐ a scientific description ☐ a proposed taxonomic description indicated above.

The deposits were received June 1, 1995 by this International Depository Authority and have been accepted.

AT YOUR REQUEST:

☒ We will inform you of requests for the strains for 30 years.

The strains will be made available if a patent office signatory to the Budapest Treaty certifies one's right to receive, or if a U.S. Patent is issued citing the strains and ATCC is instructed by the United States Patent & Trademark Office or the depositor to release said strain.

If the cultures should die or be destroyed during the effective term of the deposit, it shall be your responsibility to replace them with living cultures of the same.

The strains will be maintained for a period of at least 30 years after the date of deposit, and for a period of at least five years after the most recent request for a sample. The United States and many other countries are signatory to the Budapest Treaty.

The viability of the cultures cited above was tested June 8, 1995. On that date, the cultures were viable.

International Depository Authority: American Type Culture Collection, Rockville, Md. 20852 USA

Signature of person having authority to represent ATCC:

Annette L. Bade, Director, Patent Depository

cc: Greg D. Ferraro

Date: June 14, 1995